REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1, 5-10, 17, 19, 25, 28, 31, 40, 70-80, 83-86, 89-91, 97, 100-102, 104-107, 225, 229-232, 239-244, 246, 250-255, 282, 284-291 and 293-304 are pending after entry of the amendments set forth herein. In addition to the previously canceled claims, claims 11-16, 18, 20-22, 26-27, 29-30, 32-33, 41-54, 58-69, 81-82, 87-88, 103, 233-238, 245, 247-249 and 292 have been canceled above, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 1, 5-22, 25-33, 40-54, 58-91, 97, 100-107, 225, 229-255, 282 and 284-301 were examined. Claims 1, 5-22, 25-33, 40-54, 58-91, 97, 100-107, 225, 229-255, 282 and 284-301 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

Objections to Amendment under 35 U.S.C. Section 132(a)

In the Official Action of January 8, 2008, the Examiner objected to the "amendment filed October 25, 2007" as introducing new matter into the disclosure. The Examiner asserted that the phrase "wherein said at least one lumen is offset from a central longitudinal axis of said sheath" is not supported by the original disclosure. Applicants respectfully traverse. The Examiner is respectfully directed to the original specification at page 20, lines 22-25 which state "The is primarily performed by advancing the energy delivery portion 27 of the ablative device 26 through the ablation lumen 25 of the ablation sheath 22 which is preferably off-set from the longitudinal axis 78 thereof. The Examiner is further referred to Figs. 8 and 9 which show the lumen as being off-set from the longitudinal axis 78. The Examiner implied that because Fig. 8 shows the lumen encompassing the longitudinal axis 78, that this would exclude the lumen from being offset from the longitudinal axis. Applicants respectfully

traverse. It is respectfully submitted that any lumen that is not coaxial with the longitudinal axis of the sheath is off-set from the longitudinal axis.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the objected to the amendment filed October 25, 2007 as introducing new matter into the disclosure, as being inappropriate.

Rejection of Claim 301 under 35 U.S.C. Section 112, First Paragraph

Claim 301 was rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. The Examiner asserted that claim 301 contains subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed , had possession of the claimed invention, as the Examiner asserted that the originally filed disclosure is silent on "wherein said at least one lumen is offset from a central longitudinal axis of said sheath".

Applicants respectfully traverse. For at least the reasons noted above in regard to the traversal of the objection to the specification, Applicants respectfully submit that the specification, at least at page 20, lines 22-25, and Figs.8-9 would reasonably convey to one of ordinary skill in the art that the lumen 25 is off-set from the longitudinal axis 78 of the sheath.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 301 under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement, as being inappropriate.

Claim Rejected Under 35 U.S.C. Section 102(b) (Roth et al.)

Claim 106 was rejected under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., U.S. Patent No. 5,207,672.

Applicants thank the Examiner for the clarification in confirming that the Roth et al. reference relied upon is U.S. Patent no. 5,207,672. However, the Examiner's assertion that U.S. Patent No. 5,207,672 to Roth et al. is the only patent of record to Roth et al. is simply incorrect. U.S. Patent No. 5,823,956 to Roth et al. was submitted in an Information Disclosure Statement on December 17, 2004 and the PTO-1449 listing the same was initialed by the Examiner and entered on June 7, 2007 (see sheet 5 of 10), thereby making it of record.

Claim 106 has been amended above to further specify that the pres-shaped distal end portion of the guide catheter comprises a bendable-shape-retaining member adapted to retain a pre-formed shape of said pre-shaped distal end by returning from a relatively straightened shape to said pre-formed shape when delivered out of a lumen of a guide sheath. Support for this amendment can be found, for example, at page 7 lines 10-12 of the specification and throughout the specification.

It is respectfully submitted that Roth et al. clearly fails to disclose or inherently possess a pre-shaped distal end portion comprising a bendable shape-retaining member as recited in claim 106.

In view of the above amendment and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 106 under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., U.S. Patent No. 5,207,672, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(e) (Sinofsky et al.)

Claims 106-107, 225, 240, 243, 246, 248-249, 253, 293-295 and 297 were rejected under 35 U.S.C. Section 102(e) as being clearly anticipated by Sinofsky et al., U.S. Patent No. 6,558,365.

Applicants respectfully traverse.

In response to Applicants' previous remarks asserting that there would be no motivation to prevent rotation of the optical fiber of Sinofsky et al., the Examiner was silent. However, the Examiner did emphasize that Applicants' reliance upon Fig. 2 as a basis for argument is inappropriate since, the Examiner asserted, "Sinofsky et al. make mention of no absolute or relative sizes of the elements whatsoever and given that it is 'well-known that drawings are not considered to be drawn to scale.'".

Applicants respectfully submit that the Examiner has clearly applied an arbitrary and inappropriate double standard for interpreting the Sinofsky et al. reference. It is respectfully submitted that in order for the Examiner to conclude that Sinofsky et al. discloses an ablation sheath having an oval cross section, this necessarily requires that the Examiner is relying on the accuracy of the scale of the drawings, since Sinofsky et al. makes no mention of absolute or relative sizes of the elements in the written description, as admitted by the Examiner. If the dimensions of a circle are not drawn accurately with regard to scales of its dimensions, it can appear as an oval. There is nothing in the written description of Sinofsky et al. which would be interpreted by one of ordinary skill of the art as disclosing an oval sheath.

It is respectfully submitted that it is clearly arbitrary for the Examiner to, on the one hand, interpret Figs. 2 and 4 as clearly showing an oval sheath, but on the other hand, argue that it is clearly

inappropriate for Applicants to rely upon the scale of the very same Fig. 2.

Accordingly, if a single standard is applied to the interpretation of Fig. 2, then Sinofsky et al. fails to meet the recitations of the claims. If the Examiner applies the standard that the drawings can not be relived upon for issues of scale, then the Examiner, while discounting Applicants arguments regarding Sinofsky et al's failure to prevent rotation of the fiber, must also discount the interpretation that Sinofsky et al. discloses an oval sheath. If, on the other hand, the Examiner relies upon Figs. 2 and 4 for what they show, then the Examiner cannot arbitrarily conclude that Fig. 2 shows oval components, but that they are not drawn to scale and so the argument that relative rotation is not prevented is not supported by Fig. 2.

The Examiner further argued that even if a gap per se can be inferred form the illustrations of Sinofsky et al. that would one ordinary skill in the art would readily perceive that it would be a minimal gap provided to allow the fiber to slide without binding against the passage wall and that this arrangement would still prevent rotation. Applicants respectfully submit that the Examiner's assertion is conclusive, speculative, and wholly unsupported by the disclosure of Sinofsky et al. There is nothing in Sinofsky et al. that would suggest to one of ordinary skill in the art that the fiber of Sinofsky et al. needs to be prevented from rotating relative to the outer element that it is retained in. On the contrary, since rotation of the fiber would not alter the characteristics of the light applied thereby (as admitted by the Examiner), then there would be no reason to make efforts maintain rotational orientation of the fiber.

With regard to the Examiner's argument that any gap would allow a least partial rotation, Applicants have amended claim 107 above to recite that the energy delivery portion is transluminally slid while maintaining rotational orientation of the energy delivery portion relative to the guide catheter. Support for this amendment can be found, for example, at page 21, lines 15-24 of the specification, and throughout the specification.

The Examiner argued on page 6, first full paragraph of the Office Action dated January 8, 2008, with regard to Sinofsky et al., that "it is clear, that as the optical fiber moves, the diffusing element must also move (e.g., by compression thereof), the diffusing element is also part of the 'energy delivery portion' and clearly emits light radially". Applicants do not understand the Examiner's position regarding "compression" of the diffusing element. Light diffusing element 32 receives light transmitting optical fiber 18, see Fig. 3A and column 3, lines 19-28. There does not appear to be any disclosure of causing light diffusing element to move by moving optical fiber 18 or of compressing light diffusion element 32 with optical fiber 18. The Examiner is respectfully requested to clarify this position.

With regard to the Examiner's assertion that the diffusion element is part of the energy delivery

portion and clearly emits light radially, Applicants respectfully traverse. Light travels along the axes of the optical fibers, and then is scattered by the particles 22. The remaining light reaching mirror 24 is reflected by mirror 24 and then scattered by the particles 22, see column 3, lines 41-57. Accordingly, light from the source is only emitted axially in the direction of the axes of the optical fibers. Light that is directed radially is reflected, by scattering, not emitted.

Claim 225 has been amended to replace "radially asymmetric" with a recitation that the at least one lumen is not coaxially aligned with said ablation sheath. Support for this amendment can be found, for example, at page 20, lines 22-25, Figs.8-9, and throughout the specification. It is respectfully submitted that Sinofsky et al. clearly fails to disclose or inherently possess this feature.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 106-107, 225, 240, 243, 246, 253, 293-295 and 297 (claims 248-249 having been canceled without prejudice above) under 35 U.S.C. Section 102(e) as being clearly anticipated by Sinofsky et al., U.S. Patent No. 6,558,365, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103 (Bednarek in combination with Sinofsky et al.)

Claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-103, 296, 298 and 299 were rejected under 35 U.S.C. Section 103 as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375. The Examiner asserted that Bednarek teaches a method as claimed except for maintaining rotational alignment.

For reasons stated above with regard to the anticipatory-type rejections over Sinofsky et al., it is respectfully submitted that Sinofsky et al. also fails to teach or suggest maintaining rotational alignment.

With regard to claims 59 and 64, it is respectfully submitted that the Examiner cannot rely upon the scale of Fig 4 (or Fig. 2) of Sinofsky et al. as disclosing an oval configuration for the same reason that the Examiner has asserted that Applicant cannot rely upon Fig. 2 as showing a gap between the fiber and diffuser, i.e., since drawings are known to be not reliable as to scale.

Further, the Examiner noted U.S. Patent No. 5,314,466 in support of an argument that "the use of directionalized microwave emitters being known in the art". It is unclear whether or not the Examiner has applied U.S. Patent No. 5, 314,466. Applicants respectfully submit that if U.S. Patent No. 5,314,466 is being applied as part of the grounds of rejection here, then it should be properly included in the statement of the grounds of rejection.

With regard to claim 101, the Examiner asserted that one of ordinary skill in the art would desire

to allow the maximum energy transfer between the device and the tissue, and that this would impel one of ordinary skill in the art to employ a material with the coefficient claimed. By so concluding, the Examiner has implied that the provision of a cutout, so that no material exists between the emitter and the tissue, would allow less energy transfer to the tissue that the provision of a dielectric material therebetween. Applicants respectfully traverse and submit that the Examiner's assumption is incorrect.

With regard to key assemblies, the Examiner asserted that Sinofsky et al. discloses a key assembly that is exactly the same as that shown in Fig. 20A of the present specification. Applicants respectfully submit that Sinofsky et al. fails to disclose or suggest any key assembly whatsoever. Applicants further submit, as already noted above, that the Examiner's reliance on Sinofsky et al. as disclosing an oval arrangement is the result of an arbitrary double standard applied to the interpretation of Figs. 2 and 4. Applicants further note that rejections of claims relating to key assemblies should be made with regard to the claim language of the claim being rejected, not upon a figure in the specification. For example, Fig. 20A does not show a flexible tubular member with a key assembly to align the energy delivery portion with the distal end portion of the flexible tubular member. Rather, Fig. 20A shows the shape of a key structure of a rail device and rail receiving passage.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5, 9-10, 14-16, 25, 28, 31, 71-72, 86, 89-91, 97, 100-102, 296, 298 and 299 under 35 U.S.C. Section 103 as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al. and Cox et al.)

Claims 6-8, 12-13, 17-22, 40-42, 70, 78-79, 104-105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-105, 296, 298 and 299 above, and further in combination with Cox et al., WO 98/17187 and "the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the

device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures".

On page 12, last paragraph to page 13, first paragraph of the Office Action dated January 8, 2008, the Examiner purportedly responds to the assertion that Sinofsky et al. appear to provide no teachings to procedures and that Bednarek and Cox et al. tech only endocardial procedures. The Examiner directed Applicants to the paragraph bridging pages 11 and 12 of Cox et al., which is reproduced hereafter:

> Attention is now directed to FIGURES 1-3 where a human heart **H** is illustrated incorporating a series of strategically positioned transmural lesions throughout the right atrium **RA** and the left atrium **LA** formed within the heart treatment procedure and system of the present invention. FIGURE 1 represents the desired pattern of lesions created on the right atrium **RA**, including the posterior longitudinal right atrial lesion 50, the tricuspid valve annulus lesion valve annulus lesion 51, the pulmonary vein isolation lesion vain isolation lesion 52 and the perpendicular lesion; while FIGURE 2 represent a right, anterior perspective view of the heart **H** illustrating right atrium **RA** including a right atrial anteromedial counter lesion 55. The cumulative pattern of lesions reconstruct a main electrical conduction route between the sinoatrial node to the atrioventricular node to postoperatively preserve atrial transport function. Unlike prior surgical treatments, the system and procedure of the present invention, generally designated 56 in FIGURES 4 and 5, employ a closed-heart technique which eliminates the need for gross multiple elongated incisions of the atria to ablate heart tissue in the manner sufficient to preclude electrical conduction of reentrant pathways in the atria.

It is respectfully submitted that the above disclosure clearly fails to describe an epicardial procedure, contrary to the Examiner's implication. Further, the procedure shown in Fig. 9 of Bednarek is clearly an endocardial procedure. Because the device of Bednarek is a catheter designed to be introduced endocardially via the vasculature(see Fig. 9), there is no teaching provided by either Sinofsky et al. or Cox et al. of a procedure for using the device of Bednarek in an epicardial procedure. The device of Sinofsky et al. is a hand-held, pen like structure, not an intravascular catheter.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 6-8, 17-19, 40, 70, 78-79, 104-105, 225, 229-232, 239-242, 244, 250-252, 254-255, 282, 284-291 and 300 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71-72, 86-87, 89-91, 97, 100-105, 296, 298 and 299 above, and further in combination with Cox et al., WO 98/17187 and

"the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures", as being clearly inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al., Cox et al. and Swanson et al.)

Claims 70-79 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in combination with Swanson et al., U.S. Patent No. 6,076,012. The Examiner asserted that Swanson et al. teaches using temperature sensors to control ablation and electrodes to pace, map, etc., the heart in a maze procedure wherein the pulmonary vein is encircled. The Examiner asserted that it would have been obvious to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek, Sinofsky et al. and Cox et al. since this would enable the performance of beneficial cardiac procedures, such as maze or to employ the longitudinally translatable ablation element of the combined method of Bednarek, Sinofsky et al. and Cox et al. in the method of Swanson et al. since this can create longer lesions with a single ablation element.

Applicants respectfully traverse. Claims 70-79 depend from claim 1 and it is respectfully submitted that none of the applied references teaches or discloses maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen. Swanson contributes nothing to overcome this defect.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 70-79 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S.

Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in combination with Swanson et al., U.S. Patent No. 6,076,012, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al., Cox et al. and Kesten et al.)

Claims 80-91 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in view of Kesten et al., WO 96/35469. The Examiner asserted that Kesten et al. teaches delivering ablation devices with a pre-shaped sleeve to reach the ventricles via the peripheral veins, and that it would have been obvious to employ the sheath, delivering route and treatment region of Kesten et al. in the combined method of Bednarek et al., Sinofsky et al. and Cox et al., or to employ the directional slidable probe in a sheath of the combined method of Bednarek, Sinofsky et al, Cox et al. and Kesten et al., since this would allow the treatment of an elongated area without repositioning the device, and in either case, to treat one of the atria or ventricles.

Applicants respectfully traverse. Applicants respectfully submit that claims 80, 83-86 and 89-91 (claims 81-82 and 87-88 having been canceled without prejudice above) depend from claim 1 and it is respectfully submitted that none of the applied references teaches or discloses maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen, as Kesten et al. does not deliver ablative energy through an ablation sheath or tubular member, but extends the therapeutic device 3 distally out of the open end of the delivery catheter to apply therapy.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 80, 83-86 and 89-91 (claims 81-82 and 87-88 having been canceled without prejudice above) under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54,

58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in view of Kesten et al., WO 96/35469, as being inappropriate.

New Claims

New claims 302-304 have been presented above. Support for claim 302 can be found, for example, in original claim 106, page 13, lines 15-18 and pages 20-22 of the specification, and throughout the specification. Support for claim 303 can be found, for example, in original claim 106, page 22 of the specification, and throughout the specification. Support for claim 304 can be found, for example, in the specification at page 24, lines 9-21 and throughout the specification. The Examiner is respectfully requested to indicate the allowance of claims 302-304 in the next Official Action.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-117.

Respectfully submitted,

LAW OFFICE OF ALAN W. CANNON

Date: 4/8/08

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